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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/757,310 | 01/09/2001 | Pierre Jean Francois Layrolle | 04148-00006 | 7859 |

7590 10/27/2003
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|----------------|--------------|
| EXAMINER | |
| LAMB, BRENDA A | |
| ART UNIT | PAPER NUMBER |
| 1734 | 16 |

DATE MAILED: 10/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

| | |
|-----------------|----------------|
| Application No. | Applicant(s) |
| 09/757,310 | Layrolle et al |
| Examiner | Group Art Unit |
| LAM-B | 1734 |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- Responsive to communication(s) filed on 7/22/03.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- Claim(s) 26 - 49 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 26 - 39 and 41 - 49 is/are rejected.
- Claim(s) 40 is/are objected to.
- Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - All Some* None of the CERTIFIED copies of the priority documents have been received.
 - received in Application No. (Series Code/Serial Number) _____.
 - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ Interview Summary, PTO-413
- Notice of References Cited, PTO-892 Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____

Office Action Summary

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26-28, 30-32, 35-39 and 41-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benoit et al in view of either, Zebulske, Walter or Hoffman.

Benoit et al teaches the design of coating apparatus having a reactor vessel R-2, heating element TC, stirrer, a plurality of inlets/outlets connected to the reactor and a controlled source of carbon dioxide operatively connected to an inlet (see column 11, line 1-53 and Figure 1) Benoit et al fails to teach an implant support which is operatively connected within the reactor vessel and end use of coating apparatus for coating an implant. However, it would have been obvious to modify the Benoit et al apparatus by providing a support for the implant which is operatively connected within the vessel

since it is known to provide support for material in a reservoir such as exemplified by Zebulske which shows an inner support within the reactor, an open inner container, for a type of a material within the reactor vessel or by Hoffman or Walter which shows a porous plate which supports a granular material in a reservoir for the obvious reason to provide greater control for the coating process. Finally, Benoit et al apparatus is capable of coating implants. However, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Finally, the recitation of an aperture to avoid increasing internal pressure of the reactor vessel does not further limit applicant's invention over Benoit et al in that Benoit et al has a plurality of apertures or openings which include drain valve (drain) which as depicted drains contents from the reactor vessel R-2 and exhaust valve to atmosphere and each of these valves are obviously configured to avoid increasing internal pressure of the reactor. With respect to claims 27-28, Benoit teaches the stirrer is magnetic transmission stirrer and obvious the stirrer is capable of being controlled such that stirrer rotates at 100 rpm given the wide range of agitation speeds set forth in the Examples 1-25. With respect to claims 30-31, Benoit et al teaches valve V-2 to control flow of carbon dioxide to the reaction vessel. Although Benoit et al fails to teach the valve is a solenoid valve or an electro valve, it would have been obvious to use any conventional type of valve as valve (v-2) in the Benoit apparatus including a solenoid or electro-valve for the obvious advantage over manual control valves. With respect to

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claim 35-36, Benoit et al teaches in the examples that the volume/capacity of the reactor vessel/autoclave is 1.5 liters. With respect to claims 37 and 39, Benoit et al teaches at column 11, lines 48-53 teaches that reservoir or reactor vessel is equipped with separate cooling and heating jacket (TC) or is double jacketed as shown in Fig.. 1 to obtain various temperatures. Benoit et al also teaches in examples 1-25 that the temperature of the reaction vessel/autoclave is within the scope of the claims. With respect to claim 38, Benoit et al teaches at column 11, lines 13-25 that fluid can be heated prior to circulation of the fluid to reactor vessel/reservoir/autoclave and heating of the fluids prior to re-circulation of the fluids to the reactor thereby reads on a thermo circulator. With respect to claims 41 and 42, Benoit et al teaches that pressure and temperature within the reaction vessel/autoclave is adjusted in a controlled manner (see column 8, line 59 to column 9, line 52). Benoit et al fails to teach an automated system for controlling temperature and pressure as a function of time but obvious to do so for the advantage of automation of a process step of measure and controlling process conditions. With respect to claims 43-44, Benoit et al teaches at column 11, line 53 filtering devices are associated with Benoit coating apparatus but fails to teach the filtering device a membrane filter has pore size of 0.2 mm. However, it would have been obvious to provide as the filtering device in the Benoit et al apparatus a conventional filtering device, a filter membrane cell, optimizing pore size of the membrane cell such that are within the scope of the claim dependent on end use of apparatus. With respect to claim 32, the recitation of electrode operatively connected to reactor/autoclave does not define applicant's invention over Benoit et al since it would

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have been obvious to include an electrode in Benoit et al since conventional to measure result effect process parameters in a reactor such as pH using a conventional pH measuring means, an electrode. With respect to claim 45, the same rejection applied to claims 1, 27, 39, 30 and 32 is applied here. With respect to claim 46, same rejection applied to claim 45 is applied here. Benoit et al teaches as discussed above temperature and pressure vessel/autoclave is adjusted in a controlled manner which would infer to one skilled in the art that means are provided to adjust temperature and pressure (see column 8, line 59 to column 9, line 24). Benoit et al fails to teach an automated system for controlling temperature and pressure as a function of time but obvious to do so for advantage of automation of a process step of measuring and controlling process conditions. With respect to claims 47-49, Benoit et al teaches a number of condensers (elements C-2 and C-1) are operatively connected to the reactor.

Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benoit et al in view of Roberts et al and either Zebulske, Walter or Hoffman. Benoit et al, Walter, Hoffman and Zebulske are applied for the reasons noted above. Benoit et al fails to disclose the reactor vessel includes a coating to avoid deposition or incrustation of carbonate and calcium phosphate or is fashioned from stainless steel. However, Roberts et al providing a lining of polytetrafluoroethylene on a metal reaction vessel which is conventionally a stainless steel material to provide greater corrosion resistance of the reaction vessel. Therefore, it would have been obvious to provide in the Benoit et al reaction vessel with a polytetrafluoroethylene lining such as taught by

Roberts et al for the taught advantage of the polytetrafluoroethylene coated metal vessel-increased resistance to corrosion. The recitation that the coating avoids deposition or incrustation of carbonated calcium phosphate does not define applicant's invention over Benoit et al as modified above since the Roberts polytetrafluoroethylene coating is within the scope of coating disclosed by applicant in the instant specification.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Benoit et al in view of Wheeler et al and either Zebulske, Walter or Hoffman.

Benoit et al, Walter, Hoffman and Zebulske are applied for the reasons noted above. Benoit et al fails to teach a porous sparger. However, it would have been obvious to use any known means to introduce carbon dioxide into the Benoit et al reactor vessel such as by providing a porous sparger since it is known to introduce gaseous components into a reactor using a sparger to more thoroughly disperse the gaseous component in a vessel and obvious to use a sparger producing microbubbles such as taught by Wheeler et al for obvious advantage of greater dispersal of the gas, carbon dioxide, within the liquid.

Applicant's arguments filed July 22, 2003 have been fully considered but they are not persuasive.

Applicant's argument that Benoit et al fails to teach the use of an autoclave having the capacity of other than 1.5 liters is found to be non-persuasive. It is noted that the Benoit et al reactor capacity set forth in claims 35-36.

Applicant's argument that Benoit et al fails to teach a thermocirculator as set forth on page 10, lines 35-36 of the instant specification is found to be non-persuasive. It is

noted that applicant has claimed a thermo-circulator but has failed to claim the function of the thermo-circulator and its relationship to the other elements of the apparatus.

Therefore, the examiner maintains that Benoit et al teaches at column 11, lines 13-25 fluids can be heated prior to circulation of the fluid to the reactor/reservoir/autoclave and heating of the fluid as one is re-circulating the fluid reads on a thermocirculator

Applicant's argument of the non-obviousness of using substituting Benoit et al standard valve with a solenoid or electro valve is found to be non-persuasive. The examiner maintains that although Benoit et al fails to teach the valve is a solenoid valve or an electro-valve, it would have been obvious to use any conventional type of valve as valve (v-2) in the Benoit apparatus including a solenoid or electro-valve for the obvious advantage over manual control valves and especially since it has been held that broadly providing a mechanical or automatic means to replace manual activity which have accomplished the same result involves only routine skill in the art (see In re Venner, 120 USPQ 192).

Claim 40 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and intervening claims.

Any inquiry concerning this communication should be directed to Brenda A. Lamb at telephone number (703) 308-2056. The examiner can normally be reached on Monday and Wednesday through Friday with alternate Tuesdays off.

B.A. Lamb/dh

Brenda A. Lamb
BRENDA A. LAMB
PRIMARY EXAMINER
GROUP 1600